

Message

From: Bahadori, Tina [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=7DA7967DCAFB4C5BBC39C666FEE31EC3-BAHADORI, TINA]
Sent: 6/5/2019 1:08:32 PM
To: Woodall, George [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a617aad87171414a8b9fca5ce395a899-Woodall, George]; Vandenberg, John [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcae2b98a04540fb8d099f9d4dead690-Vandenberg, John]; Bussard, David [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cf26b876393e44f38bdd06db02dbbfe5-Bussard, David]; Lavoie, Emma [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=86ac7844f12646c095e4e9093a941623-Lavoie, Emma]; White, Paul [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e179825823c44ebbb07a9704e1e5d16-White, Paul]; Hawkins, Belinda [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=075561d171e845828ec67a945663a8e6-Hawkins, Belinda]; Thayer, Kris [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3ce4ae3f107749c6815f243260df98c3-Thayer, Kri]; Berner, Ted [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f1949c9653024d3cb4aa4c2bd69c4fde-Berner, Ted]
CC: Ross, Mary [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=98359cd1f66f46ec91d327e99a3c6909-Ross, Mary]; Burden, Susan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aca392a7aea849bfbce1fdbcb1a1ed88e-Burden, Susan]; Hotchkiss, Andrew [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=10f01ccc8611401bb34d16b71a87d3d5-Hotchkiss, Andrew]; Dutton, Steven [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=795a1526feec425f8be0b3f5c0a671c6-Dutton, Steve]
Subject: RE: EtO - summary from OAQPS meeting yesterday

Thanks George.
T.

From: Woodall, George
Sent: Wednesday, June 5, 2019 9:08 AM
To: Vandenberg, John <Vandenberg.John@epa.gov>; Bahadori, Tina <Bahadori.Tina@epa.gov>; Bussard, David <Bussard.David@epa.gov>; Lavoie, Emma <Lavoie.Emma@epa.gov>; White, Paul <White.Paul@epa.gov>; Hawkins, Belinda <Hawkins.Belinda@epa.gov>; Thayer, Kris <thayer.kris@epa.gov>; Berner, Ted <Berner.Ted@epa.gov>
Cc: Ross, Mary <Ross.Mary@epa.gov>; Burden, Susan <Burden.Susan@epa.gov>; Hotchkiss, Andrew <Hotchkiss.Andrew@epa.gov>; Dutton, Steven <Dutton.Steven@epa.gov>
Subject: RE: EtO - summary from OAQPS meeting yesterday

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George

George M. Woodall, PhD

Toxicologist

National Center for Environmental Assessment

Office of Research and Development

U.S. Environmental Protection Agency

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Physical Address: US EPA, 109 TW Alexander Drive, Research Triangle Park, NC 27709

From: Vandenberg, John

Sent: Wednesday, June 05, 2019 8:51 AM

To: Bahadori, Tina <Bahadori.Tina@epa.gov>; Bussard, David <Bussard.David@epa.gov>; Lavoie, Emma <Lavoie.Emma@epa.gov>; White, Paul <White.Paul@epa.gov>; Hawkins, Belinda <Hawkins.Belinda@epa.gov>; Thayer, Kris <thayer.kris@epa.gov>; Berner, Ted <Berner.Ted@epa.gov>

Cc: Ross, Mary <Ross.Mary@epa.gov>; Burden, Susan <Burden.Susan@epa.gov>; Hotchkiss, Andrew <Hotchkiss.Andrew@epa.gov>; Dutton, Steven <Dutton.Steven@epa.gov>; Woodall, George <Woodall.George@epa.gov>

Subject: RE: EtO - summary from OAQPS meeting yesterday

Ex. 5 Deliberative Process (DP)

Ex. 5 Deliberative Process (DP)

John

From: Vandenberg, John
Sent: Friday, May 31, 2019 3:38 PM
To: Bahadori, Tina <Bahadori.Tina@epa.gov>; Bussard, David <Bussard.David@epa.gov>; Lavoie, Emma <Lavoie.Emma@epa.gov>; White, Paul <White.Paul@epa.gov>; Hawkins, Belinda <Hawkins.Belinda@epa.gov>; Thayer, Kris <thayer.kris@epa.gov>; Berner, Ted <Berner.Ted@epa.gov>
Cc: Ross, Mary <Ross.Mary@epa.gov>; Burden, Susan <Burden.Susan@epa.gov>
Subject: RE: EtO

Ex. 5 Deliberative Process (DP)

From: Bahadori, Tina
Sent: Friday, May 31, 2019 3:27 PM
To: Bussard, David <Bussard.David@epa.gov>; Lavoie, Emma <Lavoie.Emma@epa.gov>; White, Paul <White.Paul@epa.gov>; Hawkins, Belinda <Hawkins.Belinda@epa.gov>; Thayer, Kris <thayer.kris@epa.gov>; Vandenberg, John <Vandenberg.John@epa.gov>; Berner, Ted <Berner.Ted@epa.gov>
Cc: Ross, Mary <Ross.Mary@epa.gov>; Burden, Susan <Burden.Susan@epa.gov>
Subject: RE: EtO

Ex. 5 Deliberative Process (DP)

From: Bussard, David
Sent: Friday, May 31, 2019 3:25 PM
To: Bahadori, Tina <Bahadori.Tina@epa.gov>; Lavoie, Emma <Lavoie.Emma@epa.gov>; White, Paul <White.Paul@epa.gov>; Hawkins, Belinda <Hawkins.Belinda@epa.gov>; Thayer, Kris <thayer.kris@epa.gov>; Vandenberg, John <Vandenberg.John@epa.gov>; Berner, Ted <Berner.Ted@epa.gov>
Cc: Ross, Mary <Ross.Mary@epa.gov>; Burden, Susan <Burden.Susan@epa.gov>
Subject: RE: EtO

Ex. 5 Deliberative Process (DP)

David

From: Bahadori, Tina
Sent: Friday, May 31, 2019 3:20 PM
To: Bussard, David <Bussard.David@epa.gov>; Lavoie, Emma <Lavoie.Emma@epa.gov>; White, Paul <White.Paul@epa.gov>; Hawkins, Belinda <Hawkins.Belinda@epa.gov>; Thayer, Kris <thayer.kris@epa.gov>; Vandenberg, John <Vandenberg.John@epa.gov>; Berner, Ted <Berner.Ted@epa.gov>
Cc: Ross, Mary <Ross.Mary@epa.gov>; Burden, Susan <Burden.Susan@epa.gov>
Subject: EtO

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As EPA Readies Rules, Study Backs Stricter Limits On Facilities Emitting EtO

May 31, 2019

A long-awaited EPA risk analysis has found that cancer risks from emissions of ethylene oxide (EtO) from a now-shuttered sterilization plant in a Chicago suburb could be lowered if further controls are installed at the facility, findings that suggest upcoming agency air toxics rules governing EtO emissions could seek to strengthen current requirements.

EPA released the study at a May 29 community meeting, telling those present that their estimate of “risks at recent, pre-seal order operating/emissions levels [of the Willowbrook, IL sterilizing facility] require regulatory action,” according to one of the [presentations](#).

EPA has been under increasing pressure from the Chicago area's congressional delegation to get answers and take action regarding the Willowbrook Sterigenics plant, as well as other EtO-emitting facilities in Illinois, after the agency released National Air Toxics Assessment (NATA) modeled data last summer indicating increased cancer risk near facilities emitting EtO.

The NATA finding was based in part on the agency's 2016 Integrated Risk Information System (IRIS) assessment, which found EtO to be 30 times more potent at causing cancer than previously thought and affirmed long-suspected claims that the chemical, used as an intermediate to make other chemical products like detergent, antifreeze and polyester, and to sterilize medical equipment and foods, causes breast and lymph cancers.

It also classified the substance as a known carcinogen and recommended conservative risk values that are expected to drive stricter regulatory standards.

But chemical and other industry groups are concerned that the IRIS value will drive overly conservative regulatory standards. The American Chemistry Council (ACC) last year petitioned EPA to stop using the EtO values in rules, saying it is not justified since the substance is present in ambient air at much lower concentrations than what is assumed in the IRIS assessment.

But the agency drew fire after taking comment in its proposed [proposed risk-and-technology review](#) (RTR) for the hydrochloric acid (HCl) manufacturing sector, an eight-year review of the adequacy of federal air toxics rules, on whether it should continue to rely on its conservative 2016 IRIS risk value for EtO.

Environmentalists and Democratic lawmakers charged that EPA's request for comment bolsters the chemical industry's pending petition and, if granted, would set a broad precedent that would undermine the protectiveness of the rules. Together with state

officials, they have also warned that refraining from using the IRIS value in any RTR would be unlawful as it would not comply with a Clean Air Act mandate to use “best available science.”

The dispute has been driven home by the case of the Sterigenics facility, which state officials shuttered last February under special emergency powers to address the levels of EtO emissions, and company officials are struggling to get permission to re-open from state authorities.

Cancer Risks

According to [a summary](#) of EPA’s risk assessment, the agency estimated that in “residential areas, the estimated [cancer] risks from lifetime exposure while the facility was operating ranged from less than 100 in 1 million to 1,000 in a million in areas closest to the facility.”

The document adds that the “assessment estimated that future risks would be below 100 in million -- and potentially as low as 1 in 1 million -- if the facility was more highly controlled.”

As the document explains, a “1-in-a-million risk means that 1 person out of a million people who ... breathed air containing [EtO] for a lifetime could develop cancer as a result of that exposure.” That level of risk also represents EPA’s standard for regulatory action under several authorities.

Since the NATA release, EPA has taken air samples in the town of Willowbrook, releasing the results on its website in batches. It appears that the samples were used in the risk analyses, though Sterigenics in a [May 10 letter](#) urged EPA not to do so. The company argued that there are many other sources of EtO and there is no way to tell from EPA’s sampling the sources of the EtO detected, among other concerns.

The company further argued that it “has proposed an operating scenario to the State of Illinois, which includes significant engineering changes beyond the facility’s already-state-of-the-art emission controls, under which the facility’s average hourly emissions of [EtO] would be remarkably low.”

Sterigenics estimates that with these improvements, “our annual emissions will be less than 1 [percent] of the estimated annual emissions from just the mobile sources in DuPage County, not considering the additional contributions from the myriad other [EtO] outside sources. These improvements should be considered in any risk assessment.”

One of EPA’s presentations at the community meeting in neighboring Burr Ridge Village, IL, May 24, states that the agency “is committed to working with the state of Illinois to establish a protective control strategy prior to any reopening of the facility.”

Meanwhile, EPA presentations also state that the agency plans to propose this summer new air rules on commercial sterilizers and “miscellaneous organic chemical manufacturing” facilities, both of which emit can EtO.

The latest unified agenda indicates the EPA will issue the proposed National Emission Standards for Hazardous Air Pollutants (NESHAP) for [EtO sterilizers](#) in July, with a final rule projected for December 2019. Similarly, the agenda states that the NEHSAP for the [chemical manufacturing facilities](#) is anticipated in July, with a final rule scheduled for March 2020.

A presentation by EPA air chief Bill Wehrum to the community meeting describes the rules as part of EPA's two-pronged strategy in the wake of the NATA release.

Wehrum described these prongs as 1) reviewing Clean Air Act rules for EtO-emitting facilities "to ensure that they protect the public from significant risk," pointing to the two NESHAPs and 2) "For areas with highest risk, gather additional information on emissions of [EtO]," with the aims of supporting regulatory review and reducing emissions quickly. — Maria Hegstad (mhegstad@iwpnews.com)

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From: Bussard, David
Sent: Tuesday, May 28, 2019 1:52 PM
To: Bahadori, Tina <Bahadori.Tina@epa.gov>; Lavoie, Emma <Lavoie.Emma@epa.gov>; White, Paul <White.Paul@epa.gov>; Hawkins, Belinda <Hawkins.Belinda@epa.gov>; Thayer, Kris <thayer.kris@epa.gov>
Subject: RE: EtO meeting - any agenda?

Tina,

Ex. 5 Deliberative Process (DP)

David

From: Bahadori, Tina
Sent: Tuesday, May 28, 2019 1:27 PM
To: Lavoie, Emma <Lavoie.Emma@epa.gov>; White, Paul <White.Paul@epa.gov>; Hawkins, Belinda <Hawkins.Belinda@epa.gov>; Thayer, Kris <thayer.kris@epa.gov>; Bussard, David <Bussard.David@epa.gov>
Subject: RE: EtO meeting - any agenda?

Ex. 5 Deliberative Process (DP)

From: Lavoie, Emma
Sent: Tuesday, May 28, 2019 1:26 PM
To: White, Paul <White.Paul@epa.gov>; Hawkins, Belinda <Hawkins.Belinda@epa.gov>; Bahadori, Tina <Bahadori.Tina@epa.gov>; Thayer, Kris <thayer.kris@epa.gov>; Bussard, David <Bussard.David@epa.gov>
Subject: RE: EtO meeting - any agenda?

Ex. 5 Deliberative Process (DP)

Ex. 5 Deliberative Process (DP)

-Emma

Tel: 202 564 7091

From: White, Paul

Sent: Tuesday, May 28, 2019 1:24 PM

To: Hawkins, Belinda <Hawkins.Belinda@epa.gov>; Lavoie, Emma <Lavoie.Emma@epa.gov>; Bahadori, Tina <Bahadori.Tina@epa.gov>; Thayer, Kris <thayer.kris@epa.gov>; Bussard, David <Bussard.David@epa.gov>

Subject: EtO meeting - any agenda?

Ex. 5 Deliberative Process (DP)

Tks,
Paul